



Steven Galson of the FDA has said politics played no part in his decision to deny Plan B over-the-counter status.



Lester M. Crawford, acting FDA commissioner, is said to be "comfortable" with the decision on the emergency contraceptive.

## 2 FDA Officials Urged To Resign Over Plan B

### *Lawmakers Call Decision Political*

By MARC KAUFMAN  
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A dozen members of Congress yesterday called for the resignation of the two Food and Drug Administration officials most responsible for last week's decision to keep emergency contraception a prescription-only drug.

At a news conference, Rep. Louise M. Slaughter (D-N.Y.) said Steven Galson, acting director of the FDA's Center for Drug Evaluation and Research, and Lester M. Crawford, acting FDA commissioner, allowed politics to trump science in their decision.

"The FDA's decision to ignore its own scientific advisory board and its own staff clearly demonstrates the leadership would rather pander to conservative interests than protect women's health and well-being," said Slaughter, co-chair of the Congressional Pro-Choice Caucus. She also called on the General Accounting Office, Congress's investigative arm, to probe charges that the FDA's decision on the emergency contraceptive, Plan B, was driven by politics.

A coalition of women's health and pro-choice religious groups, many of them participants in the large women's rally on the Mall last month, joined the members of Congress in calling for a review and reversal of the Plan B decision.

On Friday, 41 members of Congress, most of them Democrats, wrote their own letter to Crawford asking that the decision be reviewed and overturned.

Last Thursday, the FDA sent

the distributor of Plan B, Barr Laboratories, a "non-approvable" letter rejecting its application to make Plan B available over the counter. The FDA said the company had not provided enough information to ensure that the drug could be safely used by girls 16 and under.

The rejection came despite a 23 to 4 vote in favor of approval by an FDA expert advisory panel in December. Galson also acknowledged last week that the FDA staff that reviewed the application had recommended that it be approved.

Galson said last week that politics played no part in his decision, and yesterday the FDA's associate commissioner for external affairs, Peter Pitts, said Crawford and Galson "remain comfortable with their decision." He said the agency gave Barr Labs a clear pathway to win approval in the future.

The Plan B application was opposed by some social conservative groups, and 49 conservative members of Congress wrote a letter to President Bush in January asking that the application be rejected.

Also yesterday, Rep. Carolyn B. Maloney (D-N.Y.) announced that she would introduce legislation today requiring the FDA to review the Plan B decision and affirm that it is not based on politics.

"When a scientific panel votes 23-4 in favor of over-the-counter status but the FDA goes the other way, there has to be something at work other than science," Maloney said. "No one should object to this bill. If politics indeed didn't influence the decision, they should affirm that without fear."